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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,891	12/02/2003	John Humphreys	3220-73872	3355
23643	7590	06/03/2005	EXAMINER	
BARNES & THORNBURG 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204			VENC1, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/725,891	Applicant(s) HUMPHREYS, JOHN	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 22, 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 22-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 2, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/22/05</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group II in the reply filed on March 25, 2005, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-17 recite the trademark/trade name "FLAG." Where trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is unclear since the trademark or trade name cannot be used properly to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the

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trademark/trade name is used to identify or describe a "FLAG sequence" or a "anti-FLAG M2 monoclonal antibody" and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-14, 16 18-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ro et al., 126 PLANT PHYSIOL. 317 (2001), in view of Kay (US 3,789,116).

Ro et al. describe a method for detecting (see Title, "Characterization and Subcellular Localization") a P450 protein (see Title, "Cinnamate 4-Hydroxylase") comprising the steps of providing a recombinant P450 protein comprising an epitope (see Abstract, "C4H fused to the FLAG epitope"), contacting the P450 protein with a ligand that binds to the epitope (see p. 327, col. 1, third paragraph, "anti-FLAG monoclonal antibody") to yield a detectably labeled P450 protein (see p. 327, col. 1, third paragraph, "horseradish peroxidase-conjugated anti-mouse antibody was used"), and detecting the labeled P450 protein (see p. 327, col. 1, third paragraph, "detected using the enhanced chemiluminescence system").

Ro et al. do not describe a labeled ligand that binds to the epitope.

However, Kay teaches the use of a labeled antibody (see Title) for detecting microorganisms, cells, and proteins (see col. 1, lines 1-10). Therefore, it would have been obvious for a person of ordinary skill in the

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art to perform the method of detecting a P450 protein, as taught by Ro et al., with a labeled antibody because Kay discovered that labeled antibodies are "exceptionally specific to a given antigen" (see Abstract) and provide "superior sensitivity that assures clear and distinct readings" (see col. 1, lines 63-67).

With respect to claims 18-19, Kay teaches the use of a fluorescent-labeled antibody (see Abstract).

With respect to claim 21, Ro et al. teach the recombinant P450 protein is derived from a crude extract (see p. 327, col. 1, first paragraph, "cell culture... disrupted yeast cells... microsomal fractions").

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ro et al., 126 PLANT PHYSIOL. 317 (2001), and Kay (US 3,789,116), as applied to claims 13 and 16, and further in view of Einhauer & Jungbauer, 49 J. BIOCHEM. BIOPHYS. METHODS 455 (2001).

Ro et al. and Kay describe a method for detecting a P450 protein as substantially described supra. The aforementioned references do not teach an amino-terminal epitope sequence. The aforementioned references do not teach the use of the M2 clone of anti-FLAG™ monoclonal antibodies.

However, Einhauer & Jungbauer teach amino-terminal tagged sequences (see p. 458, lines 4-5, "the N-terminal fusion has several advantages") for purifying recombinant proteins (see Title). Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of detecting a P450 protein, as taught by Ro et al. and Kay, with an amino-terminal epitope sequence because Einhauer & Jungbauer teach that amino-terminal epitope sequences "lead to a correctly processed product" and is "stable" (see p. 458, lines 7+).

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With respect to claim 17, Einhauer & Jungbauer teach that M2 clone "is generally more applicable" (see p. 459, lines 15-17) because M2 binds both amino-terminal and carboxy-terminal fusions.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ro et al., 126 PLANT PHYSIOL. 317 (2001), and Kay (US 3,789,116), as applied to claims 13 and 18-19, and further in view of Amersham Biosciences, Application Note 80-6443-83 (1999).

Ro et al. and Kay describe a method for detecting a P450 protein as substantially described supra. The aforementioned references do not teach the use of a phosphor autoradiography imager.

However, Amersham Biosciences teaches the use of a phosphor autoradiography imager (see Title, "Storm Image Analysis Systems"). Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of detecting a P450 protein, as taught by Ro et al. and Kay, with a phosphor autoradiography imager because Amersham Biosciences discovered that phosphor autoradiography imagers provide a "direct digital image acquisition and analysis" system (see p. 4, col. 2, last sentence) for fluorescence detection, thereby obviating the need for film.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the

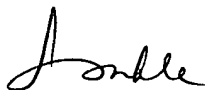
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examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/31/05